



DEPARTMENT OF AGRICULTURE

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Agricultural Marketing Service

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National Organic Program (NOP); Sunset Review (2012)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule addresses recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on April 29, 2010, October 28, 2010, and April 29, 2011. These recommendations pertain to the 2012 Sunset Review of substances on the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List). Consistent with the NOSB recommendations, this final rule continues, without change, the exemptions (use) and prohibitions for multiple listings on the National List for 5 years after their respective sunset dates. This final rule also amends the exemptions (use) for 7 substances and removes the exemptions for 3 substances on the National List.

EFFECTIVE DATES: This rule is effective June 27, 2012, except for the amendments to §§ 205.601(g) and 205.605(a), which are effective October 21, 2012. For more information on these effective dates and renewals, see the SUPPLEMENTARY INFORMATION.

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SUPPLEMENTARY INFORMATION:

I. Background.

The Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501-6522) authorizes the establishment of the National List of Allowed and Prohibited Substances (National List). The National List identifies synthetic substances that may be used in organic production and nonsynthetic (natural) substances that are prohibited in organic crop and livestock production. The National List also identifies nonagricultural nonsynthetic, nonagricultural synthetic and nonorganic agricultural substances that may be used in organic handling.

The exemptions and prohibitions granted under the OFPA are required to be reviewed every 5 years by the National Organic Standards Board (NOSB). The Secretary of Agriculture has authority under the OFPA to renew such exemptions and prohibitions. If the substances are not reviewed by the NOSB within 5 years of their inclusion on the National List and addressed by the Secretary, then their authorized use or prohibition expires under OFPA's sunset provision.

In response to the sunset provisions in the OFPA, this final rule addresses multiple recommendations submitted to the Secretary by the NOSB pertaining to substances due to expire from the National List in 2012. AMS published an Advanced Notice of Proposed Rulemaking (ANPR) in the Federal Register on March 26, 2010 (75 FR 14500), announcing the NOSB's review of exempted and prohibited substances codified at the National List of the National Organic Program (NOP) regulations and set to expire in 2012. AMS provided the comments received in response to the ANPR to the NOSB in advance of their review of these substances. Based upon the NOSB's

recommendations, AMS published a proposed rule in the Federal Register on January 12, 2012, (77 FR 1996) to address the continued use of these substances on the National List in organic production and handling.

Consistent with the recommendations from the NOSB, this final rule renews, without change, multiple exemptions (uses) and prohibitions on the National List (along with any restrictive annotations) for 5 years. This final rule also amends the exemptions for 7 substances and removes the exemptions for 3 substances on the National List. A list of these substances is provided in the Appendix to this final rule. As referenced in the proposed rule for this 2012 Sunset Review, AMS notes that the listings for nutrient vitamins and minerals at section 205.605(b) and sodium nitrate at section 205.602 will be dealt with in separate actions.

Under the authority of the OFPA, the National List can be amended by the Secretary based on recommendations developed by the NOSB. Since established, the NOP has published multiple amendments to the National List: October 31, 2003 (68 FR 61987); November 3, 2003 (68 FR 62215); October 21, 2005 (70 FR 61217); June 7, 2006 (71 FR 32803); September 11, 2006 (71 FR 53299); June 27, 2007 (72 FR 35137); October 16, 2007 (72 FR 58469); December 10, 2007 (72 FR 69569); December 12, 2007 (72 FR 70479); September 18, 2008 (73 FR 54057); October 9, 2008 (73 FR 59479); July 6, 2010 (75 FR 38693); August 24, 2010 (75 FR 51919), December 13, 2010 (75 FR 77521); March 14, 2011 (76 FR 13501); August 3, 2011 (76 FR 46595); and February 14, 2012 (77 FR 8089). Additionally, proposed amendments to the National List were published on May 5, 2011 (76 FR 25612); November 8, 2011 (76 FR 69141); January 12, 2012 (77 FR 1980); and February 6, 2012 (77 FR 5717).

II. Overview of Final Actions.

A complete overview of final actions for designated sections of the National List regulations is presented in the Appendix.¹ In the proposed rule, AMS indicated that proposed actions for each listing would be effective on the sunset date in 2012 for that listing (e.g. a listing due to sunset on October 21, 2012 would be renewed effective October 21, 2012). However, AMS determined that the effective dates for this sunset review should be streamlined to the extent possible through this final rule. Therefore, the actions pertaining to all listings, with the exception of the amendment to yeast at section 205.605(a) and the removal of sulfur dioxide at section 205.601, will be effective on one date, June 27, 2012. The effective date for each listing is specified in the Appendix. In accordance with the sunset provisions in the OFPA, the new sunset date for all listings is five years from the effective date of their renewal or amendment.

RENEWALS

Consistent with the NOSB recommendations and in consideration of the public comments received on the proposed rule (77 FR 1996), AMS is renewing multiple listings pertaining to the National List through this final rule.

This final rule continues the exemptions at section 205.601, along with any restrictive annotations, for the synthetic substances allowed for use in organic crop production as shown in the Appendix.

This final rule continues the prohibitions at section 205.602, along with any restrictive annotations, for the nonsynthetic substances prohibited for use in organic crop production as shown in the Appendix. It should be noted that the nonsynthetic, prohibited

¹ The Appendix shows a simplified listing for each substance; use categories and any restrictive annotations are not included in this overview.

substance “Ash from manure burning” was listed incorrectly in Table 1 of the proposed rule as “Ash for manure burning” (emphasis added). The correct listing is included in the Appendix of this final rule.

This final rule continues the exemptions at section 205.603, along with any restrictive annotations, for the synthetic substances allowed for use in organic livestock production as shown in the Appendix.

This final rule continues the prohibition at section 205.604, for the nonsynthetic substance prohibited for use in organic livestock production as shown in the Appendix.

This final rule continues the exemptions at section 205.605(a), along with any restrictive annotations, for the nonsynthetic, nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” as shown in the Appendix.

This final rule continues the exemptions at section 205.605(b), along with any restrictive annotations, for the synthetic, nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” as shown in the Appendix.

This final rule continues the exemptions at section 205.606, along with any restrictive annotations, for the nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” as shown in the Appendix.

NONRENEWALS

This final rule amends the National List by removing the exemptions as shown in the Appendix for the following 3 substances in organic production and handling:

Section 205.601 Synthetic substances allowed for use in organic crop production.

This final rule amends section 205.601 of the National List regulations by removing the exemption for sulfur dioxide at paragraph (g)(1) and redesignating current paragraph (g)(2) as (g) to read: (g) As rodenticides. Vitamin D₃. This amendment is effective on the sunset date for sulfur dioxide, October 21, 2012.

Section 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

This final rule amends section 205.605(b) of the National List regulations by removing the exemption for pectin (low-methoxy), and the exemption, along with its restrictive annotation, for potassium iodide. These amendments are effective on June 27, 2012.

RENEWALS WITH AMENDMENT

This final rule amends the National List regulations by amending the exemptions as shown in the Appendix for the following 7 substances in organic production and handling:

Section 205.601 Synthetic substances allowed for use in organic crop production.

This final rule amends the listing for chlorine materials at section 205.601(a)(2) to read as follows: Chlorine materials – For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions. (i) Calcium hypochlorite. (ii) Chlorine dioxide. (iii) Sodium hypochlorite. This amendment is effective on June 27, 2012.

This final rule amends section 205.601(i)(11) to add an expiration date to the listing for streptomycin to read as follows: Streptomycin, for fire blight control in apples and pears only until October 21, 2014. This amendment is effective on June 27, 2012.

This final rule amends the listing for lignin sulfonate at section 205.601(j)(4) to remove the words “floatation agent.” The new listing will read: Lignin sulfonate – chelating agent, dust suppressant. This amendment is effective on June 27, 2012. It should be noted that the amendatory language for lignin sulfonate was incorrectly listed in the proposed rule as “Lignin sulfate – chelating agent, dust suppressant” (emphasis added). This error is corrected in this final rule.

Section 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

This final rule amends the listing for yeast section 205.605(a) to read as follows: Yeast – When used as food or a fermentation agent in products labeled as “organic,” yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented. This amendment is effective on the sunset date for yeast, October 21, 2012.

Section 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

This final rule adds a restrictive annotation to the listing for colors at section 205.606(d) to read as follows: Colors derived from agricultural products – Must not be

produced using synthetic solvents and carrier systems or any artificial preservative. This amendment is effective on the sunset date for colors derived from agricultural products, June 27, 2012.

This final rule adds an expiration date to the listing for hops at section 205.606(l) to read as follows: Hops (Humulus lupulus) until January 1, 2013. This amendment is effective on the sunset date for hops, June 27, 2012.

This final rule amends the listing for pectin at section 205.606(t) to read as follows: Pectin (non-amidated forms only). This amendment is effective on June 27, 2012.

III. Related Documents.

An Advance Notice of Proposed Rulemaking with request for comments was published in the Federal Register on March 26, 2010 (75 FR 14500), to make the public aware that the exemptions and prohibitions for over 200 listings of synthetic and nonsynthetic substances in organic production and handling would expire, if not reviewed by the NOSB and addressed by the Secretary. Substances and recommendations addressed through this final rule were announced for NOSB deliberation in the following Federal Register notices: (1) March 17, 2010 (75 FR 12723); September 20, 2010 (75 FR 57194); and (2) March 4, 2011 (76 FR 12013). The proposal to address the substances in this final rule was published as a proposed rule in the Federal Register on January 12, 2012 (77 FR 1996).

IV. Statutory and Regulatory Authority

The OFPA authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k)(2) and

6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under section 205.607 of the NOP regulations. The current petition process (72 FR 2167, January 18, 2007) can be accessed through the NOP Website at <http://www.ams.usda.gov>.

A. Executive Order 12866.

This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

B. Executive Order 12988.

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This final rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in the OFPA (7 U.S.C. 6514(b)). States are also preempted by the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to the OFPA (7 U.S.C. 6519(f)), this final rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 - 624), the Poultry Products Inspection Act (21 U.S.C. 451 - 471), or the Egg Products Inspection Act (21 U.S.C. 1031 - 1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 - 399), nor the authority of the Administrator of EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)(7 U.S.C. 136 – 136(y)).

The OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small business will not be unduly or disproportionately burdened. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, AMS performed an economic impact analysis on small entities in the final rule published in the Federal Register on December 21, 2000 (65 FR 80548). AMS has also considered the economic impact of this final rule on small entities and has determined that this rule would not have a significant economic impact on a substantial number of small entities. The effect of this final rule would be to allow the continued use of multiple substances in agricultural production and handling. AMS concludes that the economic impact of the renewals and renewals with amendment of allowed substances, if any, would be minimal and beneficial to small agricultural service firms. For the substances removed or further restricted through this final action, AMS determined that their use is either not prevalent or that alternatives to their use are available to organic producers and handlers.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000 and

small agricultural producers are defined as those having annual receipts of less than \$750,000.

According to NOP's Accreditation and International Activities Division, the number of certified U.S. organic crop and livestock operations totaled over 17,000 in 2010. According to USDA, Economic Research Service (ERS) data based on information from USDA-accredited certifying agents, certified organic acreage exceeded 4.8 million acres in 2008.² In 2009, U.S. certified organic apple acreage exceeded 21,000 acres, primarily concentrated in Washington and California.³ ERS, based upon the list of certified operations maintained by the NOP, estimated the number of certified handling operations was 3,225 in 2007.⁴ AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

The U.S. sales of organic food and beverages have grown from \$3.6 billion in 1997 to nearly \$21.1 billion in 2008.⁵ The organic industry is viewed as the fastest growing sector of agriculture, representing over 3 percent of overall food sales in 2009. Between 1990 and 2008, organic food sales historically demonstrated a growth rate between 15 to 24 percent each year. In 2010, organic food sales grew 7.7%.⁶

In addition, USDA has 93 accredited certifying agents who provide certification services to producers and handlers. A complete list of names and addresses of accredited

²U.S. Department of Agriculture, Economic Research Service. 2009. *Data Sets: U.S. Certified Organic Farmland Acreage, Livestock Numbers and Farm Operations, 1992-2008*.

<http://www.ers.usda.gov/Data/Organic/>

³ Kirby, Elizabeth, and David Granatstein. *Status of Organic Tree Fruit in Washington State—2009*, Washington State University, March 2010.

⁴ U.S. Department of Agriculture, Economic Research Service, 2009. *Data Sets: Procurement and Contracting by Organic Handlers: Documentation*.

<http://www.ers.usda.gov/Data/OrganicHandlers/Documentation.htm>

⁵ Dimitri, C., and L. Oberholtzer. 2009. *Marketing U.S. Organic Foods: Recent Trends from Farms to Consumers*, Economic Information Bulletin No. 58, U.S. Department of Agriculture, Economic Research Service, <http://www.ers.usda.gov/Publications/EIB58>.

⁶ Organic Trade Association's 2011 Organic Industry Survey, <http://www.ota.com>.

certifying agents may be found on the AMS NOP web site, at <http://www.ams.usda.gov/nop> . AMS believes that most of these accredited certifying agents would be considered small entities under the criteria established by the SBA.

D. Paperwork Reduction Act.

No additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

E. Executive Order 13175.

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

F. Comments Received on Proposed Rule NOP-09-01.

AMS received approximately 40 comments on the proposed rule. AMS received comments from consumers, organic producers and handlers, trade representatives, certifying agents, ingredient manufacturers, consultants, and an environmental organization. Most comments specifically addressed proposed amendments for individual substances. A few comments were received in support of multiple or all of the substances under this sunset review. A few comments presented concerns that were not within the scope of the sunset review action.

All comments on the proposed amendments for hops and lignin sulfonate and the proposed removal of potassium iodide were supportive of the actions as proposed. Therefore, AMS is finalizing the amendments and removals as proposed through this

final rule.

Some comments suggested changes to the proposal rule for specific substances. These comments are described below in conjunction with AMS' response, including any amendments that will be addressed through this final rule.

Chlorine Materials

AMS received six comments regarding the amendment for chlorine materials allowed in crop production at section 205.601(a)(2). Comments were received from trade associations, an environmental organization and a sprout producer. Four comments supported the proposed amendment for chlorine materials, while two comments raised issues associated with the use of chlorine in sprouts.

AMS requested comments in the proposed rule on the use of chlorine in treatment of seeds for organic sprout production. Consistent with the NOSB recommendation, the proposed rule included an annotation change which, in part, intended to clarify the use of chlorine in edible sprout production. AMS specifically asked commenters to provide information on whether using the Environmental Protection Agency (EPA) labeled rate of chlorine for sprouts (20,000 ppm), followed by a rinse of potable water, is appropriate for organic production. AMS also sought input from commenters on whether there are other Food and Drug Administration (FDA) and EPA approved materials or methods suitable for sprout treatment.

One commenter responded that methods to ensure sprout safety are complex and stated that no single practice will completely eliminate pathogens. This commenter supported the clarification on chlorine as proposed and urged further development of criteria and procedures for assessing alternatives that would be both acceptable to FDA

and in organic products.

One commenter stated that there are other equally effective alternatives that would be more consistent with organic principles. This commenter, however, noted that the 20,000 ppm soak in calcium hypochlorite, a chlorine material currently allowed under the NOP regulations, is the only treatment for sprouts addressed by FDA in their guidance document.⁷ This commenter recommended that FDA clarify other treatment options that are permitted and effective for sprout treatment. AMS believes that this comment is pertinent to FDA's guidance, rather than AMS' proposed amendment for chlorine. In the absence of comments demonstrating acceptable alternatives for treatment of seed for sprouting, AMS concludes that the annotation change on chlorine specifying its allowance in sprout production is appropriate and will codify this change through this final rule.

One commenter opposed all uses of chlorine in organic production, other than unavoidable residues of chlorine from its use in treated drinking water. This commenter stated that chlorine is a reactive chemical that can combine with organic matter to form persistent organochlorines and other disinfection byproducts. For this reason, the commenter felt that added chlorine should not be used in organic crop production. The commenter requested that AMS amend the annotation for chlorine to restrict all chlorine used in direct contact with crops, in irrigation systems, and in disinfection of equipment or tools to levels no greater than the maximum residual disinfectant limit under the Safe Drinking Water Act.

AMS disagrees with the commenter on this issue. The NOSB reviewed and

⁷FDA, Guidance for Industry: Microbial Food Safety Hazards for Sprouted Seeds. October 27, 1999. <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlantProducts/ucm120244.htm>

recommended chlorine for inclusion on the National List in 1995, 2003, 2006 and 2011, according to the OFPA evaluation criteria in 7 U.S.C. 6517 and 6518. In these reviews, the NOSB assessed the impact of using chlorine on the environment and human health, but concluded that the need for this substance in some instances is necessary to ensure prevention of food borne pathogens. Consistent with the April 2011 NOSB recommendation, AMS proposed an annotation to chlorine, which would limit its direct use on crops and in soil contact to levels no higher than those found in municipal drinking water. The NOSB has not recommended any limitation on the use of chlorine for disinfecting tools and equipment when necessary to prevent spread of plant diseases. Therefore, AMS is codifying the annotation change to chlorine as proposed through this final rule.

Pheromones

AMS received one comment about the continued allowance for pheromones for insect management at section 205.601(f). The commenter objected to the categorical relisting of pheromones and indicated that the NOSB acted without sufficient information. The commenter indicated that although pheromone products are valuable to organic producers, there are many types of pheromones, and that the different types of pheromones were not reviewed by the NOSB. The commenter also indicated that the NOSB should address the use of additional ingredients in pheromone product formulations. The commenter suggested that the annotation be changed to list pheromones for insect management on section 205.601, provided that they are exempt from regulation under FIFRA (7 U.S.C. 136 – 136(y)) by 40 CFR 152.25(b).

AMS disagrees with the commenter on this issue. The NOSB is responsible for

reviewing generic materials, not specific product formulations. The NOSB has previously reviewed and recommended pheromones for inclusion on the National List according to the OFPA criteria. The NOP regulations currently allow the use of inert ingredients in pesticide formulations under a separate listing at section 205.601(m). During their sunset deliberations, the NOSB reviewed pheromones against the evaluation criteria in 7 U.S.C. 6517 and 6518 of the OFPA and concluded that they remain essential to organic production since no organic alternatives exist. The NOSB recommended that the exemption for pheromones continue as previously allowed. AMS concurs with the NOSB's evaluation and recommendation of this substance, and therefore, does not find that sufficient information was provided by the commenter to justify the addition of an annotation to the listing for pheromones on the National List. Consistent with the NOSB recommendation, AMS is renewing the listing for pheromones through this final rule as proposed.

Sulfur Dioxide

AMS received one comment that objected to the removal of sulfur dioxide from section 205.601(g) based upon its use for rodent control on organic farms. However, AMS did not receive any comments from organic producers that this substance is commonly used. Furthermore, as explained in the proposed rule, the NOSB determined that the EPA does not register any products for use as a rodenticide that contain sulfur dioxide as an active ingredient. Therefore, consistent with the NOSB recommendation, AMS is removing the listing for sulfur dioxide as a rodenticide from the National List through this final rule.

EPA List 4 – Inerts of Minimal Concern

AMS received one comment about the continued allowance for synthetic inert ingredients under the listing at section 205.601(m)(1) for “EPA List 4 – Inerts of Minimal Concern.” The commenter opposes the inclusion of EPA List 4 as a category on the National List and indicated that all substances included on EPA List 4 should be individually considered by the NOSB. The commenter also objected to the use of the term “inert” in describing other ingredients in pesticide products. The commenter noted that “inert” ingredients may be biologically active or have toxicological affects. AMS disagrees with the commenter on this issue of redefining the term “inert ingredient” at this time. The term “inert ingredient,” is defined under the NOP regulations for consistency with EPA regulations under FIFRA. AMS does not conclude that sufficient information was provided by the commenter to justify the removal of this listing from the National List. Therefore, AMS is renewing the listing for EPA List 4 through this final rule as proposed.

The commenter also suggested that the NOSB adopt a policy to transition to the individual review of inert ingredients. This comment is outside the scope of this rulemaking; however, AMS notes that a working group is currently in place to address the allowance of inerts that were previously classified as EPA List 4, since the EPA is no longer maintaining this list.

Streptomycin

AMS received eight comments on the proposed rule to relist streptomycin at section 205.601(i)(11) with an expiration date of October 21, 2014. Comments were received from a university-affiliated researcher, an agricultural pest and disease management specialist, an apple producer, a trade association, certifying agents, a

streptomycin product manufacturer and an environmental organization.

One comment supported the proposal to set October 21, 2014, as the expiration date for the use of streptomycin as recommended by the NOSB.⁸ This comment cited the following factors in support of phasing out streptomycin in organic apple and pear production: (i) potential for the substance's continued use to result in antibiotic resistance in human pathogens; (ii) inconsistency with the prohibition on antibiotic use in organic livestock production; and, (iii) incompatibility with organic and sustainable agriculture. The commenter further clarified the third point by stating that streptomycin use discourages cultural and biological controls, such as disease-resistant varieties and rootstock, site selection, careful fertilization, adequate tree spacing, proper pruning, as well as newer biological control products.

Seven comments supported the proposal to relist streptomycin, but opposed the addition of the October 21, 2014 expiration date. These commenters stated that a longer allowance time is needed and provided the following reasons for this opinion: (i) in practice, applications of streptomycin are coupled with management strategies to reduce susceptibility to fire blight and are generally limited to situations when computer models warn that an infection is likely to occur; (ii) there is a lack of viable, commercially available alternatives to streptomycin for fire blight control in apple and pear production; (iii) the research community is engaged in an ongoing effort to develop alternatives to antibiotics for controlling fire blight; (iv) streptomycin is particularly effective in humid areas where fire blight has not developed resistance; and, (v) without the availability of streptomycin to treat fire blight, some U.S. organic apple and pear producers may exit

⁸ NOSB Formal Recommendation on Streptomycin Sunset. April 29, 2011. Available on the NOP website: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5091714>

organic production and imported products could compensate for any decrease in U.S. production.

These commenters further stated that there is no assurance that current research efforts will yield any commercially viable alternative(s) to streptomycin in time for the October 21, 2014, expiration date. A number of commenters specifically cited a USDA-Organic Agriculture Research and Extension Initiative grant for the development of non-antibiotic programs for fire blight control in organic apple and pear production.

Commenters explained that the findings of this project, which started in September 2011, will not be available until 2016, and would enable the NOSB to assess the strategies for controlling fire blight without antibiotics after that time.

Comments also addressed the efficacy of several of alternatives to streptomycin, including resistant rootstocks and varieties, and biological controls, all of which the NOSB cited in its justification for recommending an expiration date. Several commenters explained that resistant rootstocks are still in development and that resistance would not convey to the upper part of the tree where the fire blight infection takes hold. Some commenters stated that apple and pear varieties have varying degrees of susceptibility to fire blight, but none are immune. One commenter reported that consumers demand newer apple and pear varieties, which are susceptible to fire blight, and stated that there is no market for other varieties. One commenter noted the slow progress in developing new varieties that exhibit favorable eating and storage qualities, as well as fire blight resistance. Some comments described biological controls as a component of an overall fire blight management strategy, which are most effective when supplemented with antibiotics. Comments also contended that years of research have not yielded any

biological control product that matches the effectiveness of streptomycin.

Commenters specifically requested that the proposed expiration date for streptomycin be deleted. In effect, such an action would renew the current listing for streptomycin on the National List for five years, until 2017, when it would be subject to sunset review.

Consistent with the NOSB recommendation, AMS is maintaining the proposed amendment to allow streptomycin for fire blight control in organic apple and pear production until October 21, 2014. During deliberations, the NOSB reviewed technical information on streptomycin in accordance with the criteria in OFPA (7 U.S.C 6517-6518) and the NOP regulations for synthetic substances on the National List (§ 205.600). The Technical Report considered by the NOSB addressed the same issues raised by the commenters to the proposed rule concerning the efficacy of alternatives to streptomycin.⁹ These alternatives include biological controls, allowed synthetic substances, the selection of varieties with low susceptibility to fire blight, and agronomic practices including careful and timely pruning, maintaining well-drained soil, limiting or excluding the use of manure and blossom removal. The NOSB is mandated by OFPA to evaluate whether alternative practices make the use of a substance such as streptomycin unnecessary. In this case, the NOSB found widespread fire blight resistance to streptomycin in apple production and continued use of apple and pear varieties that are highly susceptible to fire blight. Ultimately, the NOSB recommendation conveyed the expectation that preparation for the removal of streptomycin would augment the development and use of resistant rootstocks and cultivars, preventive management methods and the use of allowed

⁹ Technical Report on Streptomycin. March 8, 2011. Available in petitioned substances database, under “S,” at the NOP website: www.ams.usda.gov/nop

biological and chemical controls.

The NOSB also considered additional factors in its decision, including antibiotic resistance in humans and the high susceptibility of leading varieties of organic apple and pears, in terms of acreage, to fire blight. Consistent with the OFPA, the NOSB evaluated the effects of the use of streptomycin upon human health. The NOSB considered information from the Technical Report that streptomycin sprays can leave detectable residues in apple cores and skins. Based on this information, the NOSB was concerned that the continued use of streptomycin could contribute to antibiotic resistance which would be inconsistent with the principles of organic production and the OFPA criteria. The NOSB also stated that consumers expect that organic products are not produced with antibiotics.

At the April 2011 meeting, the NOSB Crops Committee put forth a proposal to extend the exemption for streptomycin until October 21, 2014. This proposal was intended to phase out use of this substance while providing a sufficient timeframe for industry members to prepare for the removal of streptomycin from the National List. At the April 2011 NOSB meeting, the NOSB took two votes on the proposal for streptomycin: one vote on their recommendation to list streptomycin with the October 21, 2014, expiration date, and one “back up vote” to relist streptomycin without restriction. The NOSB conducted these votes in accordance with their sunset review process.¹⁰ The April 2011 NOSB recommendation for streptomycin specified their intent to phase out use of the substance over time through addition of the October 21, 2014, expiration

¹⁰ The NOSB sunset review process is described on pg. 54 of the NOSB Policy and Procedures Manual. Available at NOP website: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3013893>. This process is further described in the October 28, 2010, NOSB Recommendation on Sunset Review Process. Available at NOP website: <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088004&acct=nosb>

date.¹¹ Therefore, consistent with the recommendation of the NOSB, AMS published a rule proposing the October 21, 2014, expiration date for streptomycin.

While some commenters submitted comments advocating for relisting streptomycin without restriction, AMS did not receive any new information from commenters on this issue that the NOSB had not considered during their April 2011 deliberations on streptomycin. Furthermore, AMS believes that relisting streptomycin without an expiration date would not meet the intent of the NOSB to phase out the use of this substance in organic apple and pear production over time. Therefore, consistent with the NOSB recommendation, AMS is codifying the addition of an expiration date to the listing for streptomycin through this final rule. Finally, AMS notes that extending the allowance for the use of streptomycin after the October 21, 2014, expiration date would require a petition to the NOSB. This process can be initiated in accordance with the Notice of Guidelines on Procedures for Submitting National List Petitions (72 FR 2167).

Flavors

AMS received one comment from a trade association that specifically addressed the proposed relisting of flavors, nonsynthetic sources only, on section 205.605(a). The commenter supported the continued listing of nonsynthetic flavors with the existing restriction, “must not be produced using synthetic solvents and carrier system or any artificial preservatives.” AMS is renewing the listing for flavors as proposed through this final rule.

The commenter, however, further requested that the NOP issue a guidance document to request that certifying agents use a standardized industry questionnaire to

¹¹ NOSB Recommendation on Streptomycin, April 29, 2011. Available at NOP website: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5091714>

verify compliance of the use of nonsynthetic flavors in organic handling. AMS concludes this request is beyond the scope of this final rule.

Yeast

AMS received over twenty comments in response to the proposed amendment for yeast. The majority of comments were supportive of the amendment in the proposed rule.

One commenter noted that the proposed amendment for yeast would require producers of products labeled “made with organic (specified ingredients or food group(s))” to be subject to commercial availability before using a nonorganic ingredient, which is not required for products in this labeling category. Under section 205.301(c) of the NOP regulations, products sold, labeled, or represented as “made with organic (specified ingredients or food group(s))” are not subject to the requirement that the product must not be produced using nonorganic ingredients when organic ingredients are available. AMS concludes that a modification to the proposed amendment for yeast is necessary to ensure consistency with the NOP regulations. Therefore, AMS has amended the yeast annotation through this final rule to clarify that the requirement that yeast be organic when commercially available is only applicable to products labeled “organic.”

One commenter noted that the use of the term “equivalent organic yeast” in the proposed amendment was unclear since “equivalent” was not defined. The commenter noted that organic yeast may have lower leavening activity than conventional yeast, or may only be available in a specific form (e.g. dry and not fresh), and therefore would not be considered “equivalent.” AMS notes that the amendment allows the use of conventional yeast when organic yeast is not commercially available. Under the NOP regulations, “commercially available” is defined as the ability to obtain a production

input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan. Thus, organic yeast is not required to be used if it is not available in the appropriate form or quality, as noted in the commenter's examples. To reduce confusion over the use of the term "equivalent," AMS has removed this term from the amendment in the final rule as we believe the inclusion is redundant with the existing criteria for commercial availability.

One commenter requested that AMS develop guidelines specifically for changes to the National List for which label revisions will be necessary. The commenter specifically noted that an operator presently using nonorganic yeast that successfully sources organic yeast will need to update the ingredient statement in their product labels to indicate the yeast is organic. The commenter suggested these guidelines allow at least one year for label revisions.

AMS notes that the effective date of this amendment requires that product formulations be compliant by October 21, 2012. The publication of this final rule provides almost four months of notice to the industry about this change. Sections 205.304 – 205.306 of the NOP regulations require that each organic ingredient in the ingredient statement be identified with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Therefore, if product formulations must be compliant by October 21, 2012, then the labels for these products should also be compliant with the regulations at sections 205.304 – 205.306 by the effective date for this amendment. Products entering the stream of commerce prior to the effective date do not have to be relabeled. AMS

further notes that development of broad guidelines on label use up for any National List change is beyond the scope of this rulemaking.

Two commenters requested that yeast be moved from section 205.605 of the National List to section 205.606, as an agricultural product. One commenter noted that listing yeast on section 205.605 would allow products labeled “made with organic (specified ingredients or food group(s))” to use non-organic yeast without the requirements for documenting commercial availability. The NOP has addressed the concerns for products labeled “made with organic (specified ingredients or food group(s))” by clarifying that the annotation which requires organic yeast is applicable only to products labeled “organic.” One commenter noted that yeast is an organism grown for food and that it should be considered an agricultural product for listing on section 205.606, rather than section 205.605. Based on review of the record, the NOSB considered this perspective during its deliberations before issuing its formal recommendation to the NOP; therefore, AMS has chosen to retain the listing on section 205.605, as recommended by the NOSB, rather than moving the listing to section 205.606.

One commenter was opposed to the proposed amendment for yeast and supported the existing listing. The commenter noted that organic yeast is only available in dry form, not fresh. In addition, the commenter claimed that leavening activity in organic yeast is much lower than conventional yeast and that organic yeast is costly, and, therefore, is not equivalent in performance and cost. AMS notes that the current annotation permits the use of nonorganic yeast when organic yeast is not commercially available. Under the NOP regulations, section 205.2, commercially available is defined as the ability to obtain

a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan. The commenter's concern about sourcing an appropriate form (e.g. fresh, rather than dry) or quality (e.g. better leavening activity) could be considered by the certifying agent to determine whether nonorganic yeast would be allowed under the regulations in specific applications. The higher cost of organic yeast is not one of the permitted criteria for determining commercial availability under the NOP regulations. The NOSB considered the issues raised by the commenters, and AMS concludes that the inclusion of a commercial availability clause addresses the commenter's concern about the allowance for conventional yeast when organic yeast is not available in an appropriate form, quality, or quantity.

Silicon Dioxide

The NOP received one comment stating that the listing for silicon dioxide at section 205.605(b) should be amended to reflect a December 2011 NOSB recommendation on this substance. In their December 2011 recommendation, the NOSB recommended the addition of a restrictive annotation to specify that silicon dioxide, a synthetic used in processed products, could only be used if a nonsynthetic alternative for certain uses is not commercially available. However, the December 2011 NOSB recommendation was not available when drafting the proposed rule for this 2012 Sunset Review. Therefore, consistent with the October 2010 NOSB recommendation pertaining to the 2012 Sunset Review for this substance, AMS published a proposed rule on January 12, 2012, to renew silicon dioxide at section 205.605(b) as currently listed (i.e. without annotation). Because the proposal to amend the annotation for silicon dioxide was not

included in the proposed rule and AMS did not receive public comment on such a change, AMS is not amending the annotation in this final rule. AMS is, therefore, renewing the existing listing for silicon dioxide through this final rule as proposed. AMS intends to address the December 2011 NOSB recommendation for this substance through a separate rulemaking action for National List amendments.

Xanthan Gum

AMS received one comment from a trade association in support of relisting xanthan gum; however, this commenter also suggested reclassifying the substance as nonsynthetic and relisting it at section 205.605(a) of the National List. This commenter describes xanthan gum as a natural extracellular polysaccharide. The NOSB reviewed xanthan gum in April 2010 and did not propose any change in classification at that time. Therefore, AMS is renewing the listing for xanthan gum as codified.

Pectin

In accordance with the October 2010 NOSB recommendation, the NOP proposed to remove the listing of synthetic pectin (low methoxy) at section 205.605(b), and to amend the listing for pectin (high-methoxy) at section 205.606(t) to “Pectin (non-amidated forms only).” The NOP received five comments in support of these proposed changes from trade associations, a beverage and dairy products manufacturer, and a consulting firm. The commenters agreed generally that non-amidated forms of pectin are adequate for use in organic products.

One commenter opposed the proposed changes for technical reasons. This commenter disagreed with the October 2010 NOSB recommendation that considered both low-methoxy and high-methoxy pectin to be derived from a similar non-synthetic

extraction process, with the difference in the final substance resulting from a longer extraction period. The commenter pointed out that the low-methoxy pectin is produced as a result of esterification (by removal of methyl groups, or demethylation) of high-methoxy pectin which is initially derived from citrus peel or apple pomace.¹² This commenter agreed that amidated forms of pectin (forms treated with ammonia) are not necessary for use in organic production, but noted that only low-methoxy pectin is available in amidated form. This commenter suggested that the listing at section 205.605(b) be amended to: “low-methoxy pectin, non-amidated forms only” and that the existing listing for high-methoxy pectin be retained at section 205.606.

While AMS believes that the commenter has merit regarding technical classification of the substance, the intent of the NOSB was to require that all forms of pectin used in organic products be subject to the requirement that organic sources be used when commercially available. Therefore, consistent with the intent of the NOSB, we have retained the proposed amendments for pectin in this final rule.

Colors

AMS received four comments in support of the proposed amendment to the listing for colors at section 205.606(d). The proposed listing was “Colors derived from agricultural products – Must not be produced using synthetic solvents and carrier systems or any artificial preservative.” These commenters, however, requested that AMS clarify whether synthetic substances allowed under section 205.605(b) for solvent extraction, or as carriers, preservatives or stabilizers, and which are currently allowed for use in organic colors, would also be allowed for use in nonorganic colors at section 205.606.

¹² This process is also described in the 2009 Technical Report for Non Amidated Low Methoxyl Pectin. Available at NOP website: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5087206> .

Commenters specifically referenced ascorbic acid, carbon dioxide, glycerin, silicon dioxide and tocopherols, as examples of substances listed at section 205.605(b), which are currently allowed to produce organic colors. These substances were previously recommended by the NOSB and are currently codified as allowed synthetics at section 205.605(b) of the National List. The commenters requested clarification as to whether such substances at section 205.605(b) would still be allowed in the production of nonorganic colors under the proposed amendment.

At their October 2010 meeting, the NOSB discussed the need for an annotation to clarify the allowance of synthetic solvents in the preparation of the colors listed on section 205.606.¹³ The NOSB recommended an amendment to restrict the use of synthetic solvents, carrier systems and artificial preservatives in the production of colors. However, in their recommendation, the NOSB did not address whether this restriction would apply to synthetics already listed at section 205.605(b).

The NOSB has already reviewed and recommended the synthetics listed at section 205.605(b) of the National List. Therefore, the synthetics listed at section 205.605(b) of the National List are already allowed in organic processed products, including in the formulation of colors. AMS believes the intent of the NOSB recommendation for colors is to prevent the use of synthetic substances that are not on the National List in the formulation of colors. Substances at section 205.605(b) of the National List will still be allowed in the production of nonorganic colors under the amendment.

One commenter stated that unrestricted use of synthetic solvents or carriers permitted by FDA should be acceptable in colors used for organic production. AMS

¹³ This NOSB discussion is available on the NOP website in the meeting transcript for Oct. 26, 2010 at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088302&acct=nosb>

disagrees with this comment. While certain synthetic solvents or carriers may be permitted by FDA, these synthetics would need to be petitioned and reviewed by the NOSB for inclusion on the National List under the NOP regulations.

Some commenters requested that AMS provide a one year compliance date from the effective date of the amendment to colors. Commenters stated that, while they believe that colors that comply with the amendment are available, manufacturers will need time to reformulate products that contained colors produced with synthetic solvents or carrier systems no longer allowed under the amendment. Based on the comments received, AMS understands that some product reformulation may be necessary. The effective date for this amendment is June 27, 2012, the sunset date for the current listing for colors. While this amendment is effective on June 27, 2012, AMS considers a one year period from that date as reasonable and appropriate for the industry to reformulate products in order to ensure that the amendment is effectively and rationally implemented. AMS will be conducting outreach to the industry and training for certifying agents as appropriate.

Cornstarch

AMS received one comment opposed to the continued listing of cornstarch (native) at section 205.606(w)(1) of the National List. This commenter cited several sources for organic cornstarch that include a number of types for different applications, and suggested that nonorganic cornstarch should no longer be given an exemption for organic use. The commenter also believes that nonorganic cornstarch should not be included on the National List since most nonorganic sources could be derived from genetically engineered corn.

During the October 2010 NOSB deliberations on the 2012 Sunset Review for cornstarch, the NOSB did not receive public comments objecting to relisting of cornstarch, and received several in support of relisting on section 205.606. In their review, the NOSB did not identify risks to the environment, human or animal health resulting from the use or manufacture of the substance. Based upon the NOSB's recommendation, AMS is relisting cornstarch as codified at section 205.606. AMS notes that all nonorganic ingredients, including cornstarch, used in products labeled "organic" or "made with organic (specified ingredients or food group(s))" must not be produced using excluded methods, and that organic cornstarch should be used if commercially available.

F. Effective Date

This final rule reflects recommendations submitted to the Secretary by the NOSB for the purpose of fulfilling the requirements of 7 U.S.C. 6517(e) of the OFPA. Section 7 U.S.C. 6517(e) requires the NOSB to review each substance on the National List within 5 years of its publication. The substances being renewed or reauthorized with amended annotations on the National List were most recently reauthorized for use in organic agriculture on June 27, 2007, October 21, 2007, December 11, 2007, and December 13, 2007. In the case of substances reauthorized for use on June 27, 2007 and due to expire on June 27, 2012, the substances being renewed and amended are critical to organic production and handling operations.

Accordingly, pursuant to 5 U.S.C. 553, it is found and determined that good cause exists for not postponing the effective date for amendments and renewals contained in this rule that are due to expire on June 27, 2012, until 30 days after publication in the Federal Register. The effective dates for all substances are indicated in the Appendix.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205 is amended as follows:

PART 205 – NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501-6522.

2. Section 205.601 is amended by:

A. Revising paragraph (a)(2);

B. Revising paragraph (g);

C. Revising paragraph (i)(11); and

D. Revising paragraph (j)(4) to read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

* * * * *

(a) * * *

(2) Chlorine materials – For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

* * * * *

(g) As rodenticides. Vitamin D₃.

* * * * *

(i) * * *

(11) Streptomycin, for fire blight control in apples and pears only until October 21, 2014.

* * * * *

(j) * * *

(4) Lignin sulfonate – chelating agent, dust suppressant.

* * * * *

3. Section 205.605 is amended by:

A. Revising the annotation for “Yeast” under paragraph (a);

B. Removing “Pectin (low-methoxy)” from paragraph (b); and

C. Removing the paragraph for “Potassium iodide” from paragraph (b).

The revision reads as follows:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

* * * * *

(a) * * *

* * * * *

Yeast – When used as food or a fermentation agent in products labeled as “organic,” yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.

* * * * *

4. Section 205.606 is amended by:

- A. Revising paragraph (d);
- B. Revising paragraph (l); and
- C. Revising paragraph (t).

The revisions read as follows:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled “organic”.

* * * * *

(d) Colors derived from agricultural products – Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

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(l) Hops (Humulus lupulus) until January 1, 2013.

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(t) Pectin (non-amidated forms only).

* * * * *

Dated: May 30, 2012

David R. Shipman
Administrator
Agricultural Marketing Service

Note: The following Appendix will not appear in the Code of Federal Regulations.

Appendix – Overview of Final Actions for Sunset 2012¹⁴

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
§ 205.601 Synthetic substances allowed for use in organic crop production.	Alcohols (Ethanol; Isopropanol)	April 2011	June 27, 2012	Renew
	Ammonium carbonate	April 2010*	June 27, 2012	Renew
	Aquatic plant extracts (other than hydrolyzed)	April 2010*	June 27, 2012	Renew
	Boric acid	April 2010*	June 27, 2012	Renew
	Chlorine materials at § 205.601(a)(2) (Calcium hypochlorite; chlorine dioxide; sodium hypochlorite)	April 2011	June 27, 2012	Amend: Chlorine materials – For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used

¹⁴ This Appendix shows a simplified listing for each substance; use categories and any restrictive annotations are not included in this overview.

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
				in edible sprout production according to EPA label directions.
	Coppers, fixed (Copper hydroxide; copper oxide; copper oxychloride, includes products exempted from EPA tolerance)	April 2011	June 27, 2012	Renew
	Copper sulfate	April 2011	June 27, 2012	Renew
	Elemental sulfur (3 uses)	April 2010*	June 27, 2012	Renew
	EPA List 4-Inerts of Minimal Concern	October 2010	June 27, 2012	Renew
	Ethylene gas	April 2011	June 27, 2012	Renew
	Herbicides, soap-based	April 2010*	June 27, 2012	Renew
	Humic acids	April 2010*	June 27, 2012	Renew
	Hydrated lime	April 2010*	June 27, 2012	Renew
	Hydrogen peroxide (2 uses)	April 2010*	June 27, 2012	Renew
	Lignin sulfonate at § 205.601(j)(4)	April 2011	June 27, 2012	Amend: Lignin sulfonate – chelating

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
				agent, dust suppressant.
	Lignin sulfonate at § 205.601(l)(1)	April 2011	June 27, 2012	Renew
	Lime sulfur (2 uses)	April 2010*	June 27, 2012	Renew
	Liquid fish products	April 2010*	June 27, 2012	Renew
	Magnesium sulfate	April 2011	June 27, 2012	Renew
	Micronutrients (Soluble boron products; Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt).	April 2010*	June 27, 2012	Renew
	Mulches (Newspapers or other recycled paper, without glossy or colored inks; Plastic mulch and covers)	April 2011	June 27, 2012	Renew
	Newspapers or other recycled paper, without glossy or colored inks	April 2011	June 27, 2012	Renew

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
	Oils, horticultural-narrow range oils as dormant, suffocating, and summer oils (2 uses)	April 2010*	June 27, 2012	Renew
	Pheromones	April 2011	June 27, 2012	Renew
	Potassium bicarbonate	April 2010*	June 27, 2012	Renew
	Soap-based algicide/demosers	April 2010*	June 27, 2012	Renew
	Soaps, ammonium	April 2010*	June 27, 2012	Renew
	Soaps, insecticidal	April 2010*	June 27, 2012	Renew
	Sodium silicate	April 2011	June 27, 2012	Renew
	Sticky traps/barriers	April 2010*	June 27, 2012	Renew
	Streptomycin	April 2011	June 27, 2012	Amend: Streptomycin, for fire blight control in apples and pears only until October 21, 2014.
	Sucrose octanoate esters (CAS #s—42922-74-7; 58064-47-4)	April 2010*	June 27, 2012	Renew

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
	Sulfur dioxide	April 2011	October 21, 2012	Remove
	Vitamin B ₁ , C, and E	April 2010*	June 27, 2012	Renew
	Vitamin D ₃	April 2011	June 27, 2012	Renew
§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.	Arsenic	April 2010*	June 27, 2012	Renew
	Ash from manure burning	April 2010*	June 27, 2012	Renew
	Lead salts	April 2010*	June 27, 2012	Renew
	Potassium chloride	April 2010*	June 27, 2012	Renew
	Sodium fluoaluminate (mined)	April 2010*	June 27, 2012	Renew
	Sodium nitrate	April 2011	--	Addressed in separate rulemaking action
	Strychnine	April 2010*	June 27, 2012	Renew
	Tobacco dust (nicotine sulfate)	April 2010*	June 27, 2012	Renew
§ 205.603 Synthetic substances allowed for use in organic livestock production.	Alcohols (Ethanol; Isopropanol)	October 2010	June 27, 2012	Renew
	Aspirin	October 2010	June 27, 2012	Renew
	Atropine (CAS #–51–55–8)	April 2010*	June 27, 2012	Renew
	Biologics - Vaccines	April 2010*	June 27, 2012	Renew

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
	Butorphanol (CAS #-42408-82-2)	April 2010*	June 27, 2012	Renew
	Chlorhexidine	April 2010*	June 27, 2012	Renew
	Chlorine materials (Calcium hypochlorite; chlorine dioxide; sodium hypochlorite)	October 2010	June 27, 2012	Renew
	Copper sulfate	October 2010	June 27, 2012	Renew
	Electrolytes	April 2010*	June 27, 2012	Renew
	EPA List 4-Inerts of Minimal Concern	October 2010	June 27, 2012	Renew
	Excipients	April 2010*	June 27, 2012	Renew
	Flunixin (CAS #-38677-85-9)	April 2010*	June 27, 2012	Renew
	Furosemide	October 2010	June 27, 2012	Renew
	Glucose	October 2010	June 27, 2012	Renew
	Glycerine	October 2010	June 27, 2012	Renew
	Hydrogen peroxide	April 2010*	June 27, 2012	Renew
	Iodine (2 uses)	April 2010*	June 27, 2012	Renew
	Ivermectin	April 2010*	June 27, 2012	Renew

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
	Lidocaine	April 2010*	June 27, 2012	Renew
	Lime, hydrated	April 2010*	June 27, 2012	Renew
	Magnesium hydroxide (CAS #–1309–42–8)	April 2010*	June 27, 2012	Renew
	Magnesium sulfate	October 2010	June 27, 2012	Renew
	Mineral oil	April 2010*	June 27, 2012	Renew
	Oxytocin	April 2010*	June 27, 2012	Renew
	Peroxyacetic/peracetic acid (CAS #–79–21– 0)	April 2010*	June 27, 2012	Renew
	Phosphoric acid	April 2010*	June 27, 2012	Renew
	Poloxalene (CAS #– 9003–11–6)	April 2010*	June 27, 2012	Renew
	Procaine	April 2010*	June 27, 2012	Renew
	Sucrose octanoate esters (CAS #s— 42922–74–7; 58064– 47–4)	April 2010*	June 27, 2012	Renew
	Tolazoline (CAS #– 59–98–3)	April 2010*	June 27, 2012	Renew
	Trace minerals	April 2010*	June 27, 2012	Renew
	Vitamins	April 2010*	June 27, 2012	Renew
	Xylazine (CAS #–	April 2010*	June 27, 2012	Renew

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
	7361–61–7)			
§ 205.604 Nonsynthetic substances prohibited for use in organic livestock production.	Strychnine	April 2010*	June 27, 2012	Renew
§ 205.605(a) Nonsynthetic, nonagricultural substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”	Acids (Alginic; citric; lactic)	April 2010*	June 27, 2012	Renew
	Bentonite	April 2010*	June 27, 2012	Renew
	Calcium carbonate	April 2010*	June 27, 2012	Renew
	Calcium chloride	April 2010*	June 27, 2012	Renew
	Dairy cultures	April 2010*	June 27, 2012	Renew
	Diatomaceous earth	April 2010*	June 27, 2012	Renew
	Enzymes	April 2011	June 27, 2012	Renew
	Flavors	October 2010	June 27, 2012	Renew
	Kaolin	April 2010*	June 27, 2012	Renew
	Magnesium sulfate	October 2010	June 27, 2012	Renew

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
	Nitrogen	April 2010*	June 27, 2012	Renew
	Oxygen	April 2010*	June 27, 2012	Renew
	Perlite	April 2010*	June 27, 2012	Renew
	Potassium chloride	April 2010*	June 27, 2012	Renew
	Potassium iodide	April 2011	June 27, 2012	Renew
	Sodium bicarbonate	April 2010*	June 27, 2012	Renew
	Sodium carbonate	April 2010*	June 27, 2012	Renew
	Waxes (Carnauba wax; Wood resin)	April 2010*	June 27, 2012	Renew
	Yeast (Autolysate; Bakers; Brewers; Nutritional; Smoked)	October 2010	October 21, 2012	Amend: Yeast – When used as food or a fermentation agent in products labeled “organic”, yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when organic yeast is not commercially available. Growth on

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
				petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.
§ 205.605(b) Synthetic, nonagricultural substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”	Alginates	April 2010*	June 27, 2012	Renew
	Ammonium bicarbonate	April 2010*	June 27, 2012	Renew
	Ammonium carbonate	April 2010*	June 27, 2012	Renew
	Ascorbic Acid	April 2010*	June 27, 2012	Renew
	Calcium citrate	April 2010*	June 27, 2012	Renew
	Calcium hydroxide	April 2010*	June 27, 2012	Renew
	Calcium phosphates (monobasic; dibasic; tribasic)	April 2010*	June 27, 2012	Renew
	Carbon dioxide	April 2010*	June 27, 2012	Renew
	Chlorine materials (Calcium hypochlorite; chlorine dioxide; sodium	October 2010	June 27, 2012	Renew

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
	hypochlorite)			
	Ethylene	April 2010*	June 27, 2012	Renew
	Ferrous sulfate	October 2010	June 27, 2012	Renew
	Glycerides (mono; di)	April 2010*	June 27, 2012	Renew
	Glycerin	April 2010*	June 27, 2012	Renew
	Hydrogen peroxide	April 2010*	June 27, 2012	Renew
	Magnesium carbonate	April 2010*	June 27, 2012	Renew
	Magnesium chloride	April 2010*	June 27, 2012	Renew
	Magnesium stearate	April 2010*	June 27, 2012	Renew
	Nutrient vitamins and minerals	April 2011	--	Addressed in separate rulemaking action
	Ozone	April 2010*	June 27, 2012	Renew
	Pectin (low-methoxy)	October 2010	June 27, 2012	Remove
	Phosphoric acid	October 2010	June 27, 2012	Renew
	Potassium acid tartrate	April 2010*	June 27, 2012	Renew
	Potassium carbonate	April 2010*	June 27, 2012	Renew

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
	Potassium citrate	April 2010*	June 27, 2012	Renew
	Potassium hydroxide	April 2010*	June 27, 2012	Renew
	Potassium iodide	April 2011	June 27, 2012	Remove
	Potassium phosphate	April 2010*	June 27, 2012	Renew
	Silicon dioxide	October 2010	June 27, 2012	Renew
	Sodium citrate	October 2010	June 27, 2012	Renew
	Sodium hydroxide	October 2010	June 27, 2012	Renew
	Sodium phosphates	October 2010	June 27, 2012	Renew
	Sulfur dioxide	October 2010	June 27, 2012	Renew
	Tocopherols	April 2011	June 27, 2012	Renew
	Xanthan gum	April 2010*	June 27, 2012	Renew
§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed	Casings, from processed intestines	April 2010*	June 27, 2012	Renew
	Celery powder	April 2010*	June 27, 2012	Renew
	Chia (<u>Salvia hispanica L.</u>)	April 2010*	June 27, 2012	Renew
	Colors (Annatto extract color; Beet	October 2010	June 27, 2012	Amend: Colors derived from

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
products labeled as “organic.”	juice extract color; Beta-carotene extract color; Black currant juice color, Black/purple carrot juice color; Blueberry juice color; Carrot juice color; Cherry juice color; Chokeberry – Aronia juice color; Elderberry juice color; Grape juice color; Grape skin extract color; Paprika color; Pumpkin juice color; Purple potato juice color; Red cabbage extract color; Red radish extract color; Saffron extract color; Turmeric extract color). CAS numbers are provided in the Renewals with Amendment section.			agricultural products – Must not be produced using synthetic solvents and carrier systems or any artificial preservative.
	Cornstarch (native)	October 2010	June 27, 2012	Renew
	Dillweed oil (CAS # 8006-75-5)	April 2010*	June 27, 2012	Renew

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
	Fish oil (Fatty acid CAS #'s 10417-94-4 and 25167-62-8)	April 2010*	June 27, 2012	Renew
	Fructooligosaccharides (CAS#308066-66-2)	October 2010	June 27, 2012	Renew
	Galangal, frozen	April 2010*	June 27, 2012	Renew
	Gelatin (CAS # 9000-70-8)	April 2010*	June 27, 2012	Renew
	Gums (Arabic; Guar; Locust bean; Carob bean)	April 2010*	June 27, 2012	Renew
	Hops (<u>Humulus lupulus</u>) at §205.606(l)	October 2010	June 27, 2012	Amend: Hops (<u>Humulus lupulus</u>) until January 1, 2013
	Inulin, oligofructose enriched (CAS # 9005-80-5)	October 2010	June 27, 2012	Renew
	Kelp	April 2010*	June 27, 2012	Renew
	Konjac flour (CAS # 37220-17-0)	April 2010*	June 27, 2012	Renew
	Lemongrass, frozen	April 2010*	June 27, 2012	Renew
	Orange shellac – unbleached (CAS # 9000-59-3)	April 2010*	June 27, 2012	Renew
	Pectin (high-methoxy)	October 2010	June 27, 2012	Amend: Pectin (non-amidated forms only).

National List Section	Substance	NOSB Meeting	Effective Date	Final Action
	Peppers (chipotle chile)	April 2010*	June 27, 2012	Renew
	Sweet potato starch	April 2010*	June 27, 2012	Renew
	Turkish bay leaves	April 2010*	June 27, 2012	Renew
	Wakame seaweed (<u>Undaria pinnatifida</u>)	April 2010*	June 27, 2012	Renew
	Whey protein concentrate	October 2010	June 27, 2012	Renew

*The NOSB originally recommended that these substances be relisted during their April 2010 meeting. Since public comments were still being accepted for these substances, the NOSB decided to reaffirm their recommendations on these substances at the October 2010 meeting after analyzing all public comments.

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